

Multivariate Predictors of CIN	Patients without CRF OR (95%CI), p-value	Patients with CRF OR (95%CI), p-value
Diabetes	1.45 (1.26-1.67) p<0.0001	1.78 (1.34-2.37) p<0.0001
Severe CHF	3.44 (2.54-4.65) p<0.0001	2.41 (1.55-3.73) p<0.0001
Contrast/BSA ratio	1.02 (1.01=1.02) p<0.0001	1.01 (1.00-1.01) p<0.0001
Creatinine Clearance	1.02 (1.01-1.02) p<0.0001	0.98 (0.98-0.99) p=0.0003
Female Gender	1.25 (1.08-1.43) p=0.0047	p=NS
Age	1.04 (1.03-1.05) p<0.0001	p=NS

### 1173-8 Intracoronary Beta-Radiation Therapy for Long Lesions in Native Coronary Vessels

Goran R. Stankovic, Antonio Colombo, Carlo Di Mario, Remo Albiero, Nicola Corvaja, Takuro Takagi, Konstantinos Toutouzas, Antonio Amato, Ginevra Sivieri, Roberto Orecchia, Centro Cuore Columbus, Milan, Italy.

**Background:** This study evaluates early and late clinical and angiographic outcome of patients with long (>20mm) de novo or in-stent restenotic lesions in native coronary vessels treated with beta radiation for restenosis prevention.

**Methods and results:** Between April 1999 and December 2000, 84 consecutive patients, with 117 lesions longer than 20mm in native coronary vessels, were successfully treated using 90-Strontium/Yttrium radiation source. The reference vessel size was 2.49±0.5 mm, and the mean lesion length 28.7±8.6 mm. Stents were implanted in 43.6% of the lesions. Radiation dose delivered was 18.5±3.3 Gy at 2 mm from the center of the source, with a mean dwell time of 269±122 sec, and using manual pullback technique in 21% of lesions. Ticlopidine was prescribed for 3 months in the first 29 patients, subsequently for 6 months without stenting or for 1 year with stent implantation. Clinical follow-up was obtained for all patients after 16.4±6.7 months. Major adverse cardiac events, a composite of death, Q-wave myocardial infarction and target lesion revascularization, occurred in 19 patients (22.6%). Late thrombosis occurred in 2 patients (2.4%) treated with stents at the time of radiation, and after discontinuation of ticlopidine.

Follow-up angiography was performed in 74 patients (88%). Angiographic restenosis (>50% diameter stenosis of the analysis segment) was present in 27/103 lesions (26.2%). Target lesion and target vessel revascularization rates were 21.4% and 30.8%, respectively.

**Conclusion:** Intracoronary beta radiation can be safely and effectively used to treat long coronary lesions. Long term combined antiplatelet therapy is necessary for patients who receive new stents at the time of the radiation treatment.

### 1173-9 Efficacy of Long Radiation Treatment in Native In-Stent Restenosis: A Subanalysis From the RENO Registry

Dietrich Baumgart, T. Limpikankit, P. Serruys, A. Colombo, S. Silber, E. Eckhout, P. Urban, R. Bonan, A. Zeiher, A. H. Gershlick, G. Dangas, A. A. Lansky, R. Mehran, G. W. Stone, M. B. Leon, Cardiovascular Research Foundation, New York, New York, University of Essen, Essen, Germany.

**Background:** The effectiveness of intracoronary radiation therapy of diffuse in-stent restenosis (ISR) with Strontium-90 Beta sources is unknown.

**Methods:** The RENO registry is a post market prospective surveillance study enrolling consecutive patients with ISR at 46 European centers using the Novoste Beta-Cath™ system. Patients were treated with approved interventional devices, followed by Strontium-90 Beta-radiation treatment. Of the 1098 patients enrolled in the trial, 139 had diffuse native coronary ISR treated with a stepping technique using a 30, 40, or 60mm source train or a single 60mm source train. The historical control group was the placebo arm of the WRIST and LONG WRIST studies (N=94).

**Results:** Baseline characteristics were similar between two groups except for more diabetics in placebo. Brachytherapy success (<50% residual stenosis and successful delivery of the radiation device) was 99.3% in the RENO group. Clinical follow-up at 6 months was available in >96%. The results are shown in the table.

**Conclusion:** Beta-radiation with Sr-90 using either a stepping (pullback) technique or a single 60mm source train to treat patients with diffuse, long native ISR lesions is effective and results in significant reductions in TVR by 75% and MACE by 72% without any increase in the late thrombosis rates compared to historical controls.

	RENO Long Radiation (N=139)	WRIST Placebo (N=94)	p-Value
Diabetes (%)	21.9%	37.2%	0.02
Lesion length (mm)	35.33 ± 17.89	27.97 ± 11.84	0.0003
TVR at 6 months	14.9%	60.6%	<0.0001
MACE at 6 months	17.9%	64.9%	<0.0001
Total occlusion at 6 months	12.2%	9.9%	NS

### 1173-10

### Feasibility and Safety of a Novel Cryoangioplasty System

Mitsuyasu Terashima, Yasuhiro Honda, Frederick S. Goar, James D. Joye, Kristine Tatsutani, Margaret Yoklavich, Paul G. Yock, Peter J. Fitzgerald, Stanford University, Stanford, California, El Camino Hospital, Mountain View, California.

**Background:** Previous cryosurgical studies have indicated that freezing arterial tissues *in vivo* is followed by a benign healing process largely devoid of neointimal proliferation, suggesting a potential beneficial impact on restenosis following intervention. This study is designed to evaluate feasibility and safety of a newly developed cryoangioplasty (CP) system in a porcine coronary model.

**Methods:** The cryoangioplasty system (CryoPlasty™, CryoVascular Systems, Inc.) consists of a balloon-based catheter and an inflation unit, which delivers liquid nitrous oxide through the catheter and inflates the balloon to a predetermined pressure and temperature. We assessed the safety and performance characteristics of CP system at a sub-zero treatment temperature, compared with those of a control treatment (conventional PTCA) using a similar balloon to artery ratio and pressure conditions. Twelve animals were assigned to 3-day or 28-day follow-up (6 animals per group). Each animal underwent PTCA in one of the coronary arteries and CP in up to two of the remaining arteries (6 vessels with PTCA in both groups, 9 vessels and 12 vessels with CP in 3-day and 28-day follow-up, respectively). Angiography was performed at baseline, following treatment, and follow-up, and changes in lumen diameter and % diameter stenosis were analyzed by quantitative coronary angiography.

**Results:** No adverse events (including side branch occlusion or distal coronary flow limitation) were observed in any group. No significant loss of lumen diameter or increment of % diameter stenosis was found at either 3-day or 28-day follow-up in the CP group. At 28-day follow-up, mean % diameter stenosis in the CP group was 4.6%, compared with 12.5% in the PTCA group (p<0.05).

**Conclusions:** This study demonstrates the feasibility and safety of the cryoangioplasty system for use in the coronary arteries and a possible beneficial effect on chronic vascular reaction following intervention.

### 1173-11

### Are Older Women, Compared to Older Men, at Higher Risk During Percutaneous Coronary Intervention? Results From the Danish PTCA Registry

Lisette O. Jensen, Per Thayssen, Eli Kassis, Klaus Rasmussen, Kari Saunamäki, Leif Thuesen, Department of Cardiology Odense University Hospital, Odense, Denmark.

**Background:** Older patients are at higher risk during percutaneous coronary intervention (PCI). Whether this increased risk is gender related is not known. In order to evaluate this issue further, data from the Danish PTCA Registry were analysed for the 3-year period 1996-1998. During this period data from all PCI procedures in Denmark were prospectively recorded in a central database.

**Methods:** Angiographic baseline characteristics, outcome of PCI and procedural complications were analysed in a total of 8,187 consecutive procedures (6,896 patients, 11,472 lesions dilated).

**Results:** In patients ≤ 70 year women were significantly older than men (58.0 vs. 56.5; p < 0.0001), but no significant gender difference in age was seen in patients > 70 year.

	≤ 70 year		> 70 year		p
	men	women	men	women	
Number of patients	5,242	1,654	822	469	
Age (Year)	56.5	58.0	74.8	75.0	
Left ventricle ejection fraction (%)	60.3	62.1	56.5	61.1	*
Coronary narrowing severity (%)	84.6	83.2	84.8	84.2	*
Number of 1 vessel disease (%)	60.1	69.2	45.5	53.9	**
Angiographic primary success rate (%)	87.8	89.2	87.1	85.8	*
Rate of stenting (%)	58.1	56.2	58.6	57.8	
MACE (%)	4.2	4.9	8.4	10.4	*
Emergency CABG (%)	0.9	1.0	1.0	1.3	
Myocardial infarction (%)	2.9	3.7	5.8	6.6	*
Death (%)	0.4	0.2	1.6	2.6	*

M = men, W = women; MACE = major adverse coronary events (emergency CABG, non-fatal myocardial infarction (q-wave and non-q-wave myocardial infarction), and death) within 24 hours after index procedure.

\*age but not gender as independent predictor, p < 0.0001

\*\*age and gender as independent predictor, p < 0.0001

Logistic regression analysis showed, that age, but not gender, was an independent predictor of angiographic primary success rate, MACE, myocardial infarction and death.

**Conclusion:** Older patients had significant more complications after PCI, however no significant gender difference with regard to complications after PCI, neither in patients ≤ 70 year nor in patients > 70 year could be demonstrated.